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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,929	08/29/2006	Patrick Leahy	KEL01 P-146	6150

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EXAMINER	
MCEVOY, THOMAS M	

ART UNIT	PAPER NUMBER
3731	

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06/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,929	LEAHY, PATRICK	
	Examiner	Art Unit	
	THOMAS MCEVOY	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 6-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 6-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 28 is objected to because of the following informalities: the claim is listed as "currently amended" but does not appear to be amended.

Claim Rejections - 35 USC § 102

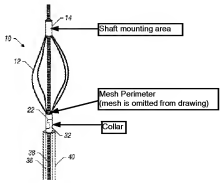
2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6-15, 17-20 and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kónya et al. (US 6,368,338).

Regarding claim 1, Kónya et al. disclose a device capable of use in parietal surgery, the device comprising a body 40; a parietal surgical implant 10 (capable of implanting in a cavity wall), the parietal surgical implant being locatable in a collapsed state about or within the body (Figure 15), the parietal surgical implant being adapted to be displaceable between the collapsed state and an expanded state (Figure 14 vs. Figure 15); and means for expanding the parietal surgical implant from the collapsed state into the expanded state (e.g., shaft 36, connection members 22 and 32). The parietal surgical implant is locatable within the body/sleeve 40 is provided for retaining the parietal surgical implant within the body in the collapsed state, the sleeve is operable to expose the parietal surgical implant (Figure 14 vs. Figure 15). Regarding claims 6, 7, 30 and 31, the proximal end of sleeve 40 and shaft 36 may be held as

handles to effect displacement thus acting as actuators (col. 17, lines 18-32 and col. 20, lines 6-9). Regarding claim 8, the proximal end of shaft 36 (the actuator) is slidably engaged with the body/sleeve 40. Regarding claim 9, the parietal surgical implant comprises a mesh having a mesh perimeter (at proximal end of mesh) and a shaft mounting area, the mesh being mounted to a shaft (the mesh is mounted to the shaft 38 at its distal end via collar 14); and the expanding means 36/32 is slidably mounted about the shaft, the expanding means being displaceable towards the mesh, in order to urge the mesh towards the expanded state (shaft 36 can be moved distally, towards the mesh to deploy the implant; col. 16, line 64 to col. 17, line 6). Regarding claims 10 and 11, the expanding means comprises a collar 32 slidably mounted about the shaft, and a plurality of arms 12 mounted between the collar and an arm mounting position of the mesh 16 (the arms are mounted to many positions of the mesh; some of which are between the collar and the shaft mounting area which is at the distal end of the mesh), the arm mounting position being spaced apart from the shaft mounting area (Figure 17). Regarding claims 12 and 13, the some of the mounting positions of the arms are at or near the mesh perimeter and spaced apart (as evident from Figure 19 for example), which are also spaced from the shaft mounting area (the distal end of the mesh at collar 14). See diagram below:



Regarding claim 14, the shaft mounting area is substantially centrally located within the mesh as seen in Figure 20. Regarding claim 15, the mesh can be expanded to a spherical shape or even further to a disc-like shape (Figures 6 and 22). The arm mounting positions as explained above are spaced around the mesh perimeter which is at the proximal end of the mesh. Regarding claim 17, the mesh is separable from the shaft (Figure 21). Regarding claim 18, the mesh and the shaft are capable of press fit engagement. Regarding claim 19, the shaft can be formed from nitinol (col. 14, lines 44-46). Regarding claim 20, collar 14 may be regarded as an abutment against which the mesh is seated. Regarding claim 24, the Kónya et al. device is capable of being reused and therefore a second implant may be regarded as a replacement part. Regarding claims 25-27, see claims 9-11 above. Regarding claims 28 and 29, Kónya et al. disclose that the implant can be secured to a surgical site (Figure 21).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 9, 16, 21, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gifford et al. (US 6,375,668 B1).

Regarding claims 1 and 16, Gifford et al. disclose a device capable of use in parietal surgery, the device comprising a body 8; a parietal surgical implant 30 (capable of implanting in a cavity wall), the parietal surgical implant being locatable in a collapsed state about or within the body, the parietal surgical implant being adapted to be displaceable between the collapsed state and an expanded state (Figure 4 vs. Figure 5); and means for expanding the parietal surgical implant from the collapsed state into the expanded state (e.g., shafts 10 and 60). It is unclear whether the body can cover and uncover the implant but Gifford et al. disclose that the implant and body should be movable relative to eachother so that the implant can be retrieved into the body (col. 6, lines 61-67). It would have been obvious to one of ordinary skill in the art to have made the body/sleeve operable to cover or uncover the implant so that it can be more easily retrieved. Alternately, it would have been obvious to one of ordinary skill in the art to have made either member 6 or 8 (either could be the body) movable relative to the implant so that their position could be adjusted during surgery. Regarding claims 9 and 16, the implant has a mesh with a perimeter and a shaft mounting area 52 (Figure 2). The expanding means 10 is slidable about shaft 60. The shaft and expansion means can be pulled towards eachother to effect expansion of the mesh (col. 6, lines 40-60). Regarding claim 21, the Figure 11-13 embodiment shows an implant which is in contact

with the body/sleeve 8 which is expanded by an inflatable balloon which is in contact or on the body (col. 7, lines 32-37). Regarding claim 23, the implant can comprise a biodegradable material (col. 6, line 1).

Response to Arguments

7. Applicant's arguments filed March 10th 2009 have been fully considered but they are not persuasive. Applicant has argued that the sleeve is a separate part from the body. Examiner respectfully disagrees and believes that, as claimed, the sleeve can be any portion of the body surrounding the implant. Furthermore, the only way for Applicant's disclosure to enable the pending claims is to consider member 24/32 as both the body and the sleeve. There is no disclosure for the implant being retained within member 12.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571) 270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/18/09